Exhibit B

Deposition of:

Rebecca Betensky , Ph.D.

July 26, 2016

In the Matter of:

Clare-Austin vs. C.R. Bard

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doing an analysis of particular adverse events that may have been associated with those drugs.

Q. And my understanding is, your analysis there depended on a database called FAERS, F-A-E-R-S?

A. I used the FAERS database for that analysis.

Q. And for the analysis that you did in this case, did you use the MAUDE database?

A. This case, today's case?

Q. Yes.

A. I used information from the MAUDE database.

Q. And when you say information from the MAUDE database, you are talking about calculations that Bard itself made based on that database?

A. I'm talking about data that was provided from Bard that was taken from that database, in addition to their own data.

Q. You in this case did not make an independent research of the MAUDE database, did you?

A. I did not.

Again, let me clarify. So I certainly did analysis and you might want to call it research on the MAUDE database. I did not myself go into the MAUDE database website and extract data, but I did

Simon Nitinol filter?

A. I don't recall.

Q. Now, you are not a medical doctor; correct?

A. That's correct.

Q. And you do not treat patients?

A. Correct.

Q. You're not a radiologist?

A. Correct.

Q. You're not an expert in human anatomy; correct?

MR. MANKOFF: Object to form.

A. Correct.

Q. Have you ever seen an inferior vena cava filter?

A. I've seen photographs of some.

Q. Prior to being retained to work in this case on this litigation, had you ever seen a photograph of an inferior vena cava filter?

A. I don't know.

Q. You're not an expert in blood clots or hematology; correct?

MR. MANKOFF: Object to form.

A. I could certainly do -- I'm certainly a statistical expert in any aspect of clots or hematology that -- yes.

Q. But only from the statistical standpoint, not from the medical standpoint; correct?
A. Correct.
Q. And you're not an expert in cardiology?
MR. MANKOFF: Object to form.
A. So I'd give the same answer there.
Q. Prior to your work in this litigation, you had never done any research regarding inferior vena cava filters, had you?
A. As far as I can remember, I did not.
Q. And never published anything?
A. Again --
MR. MANKOFF: Object to form.
A. -- as far as I can remember. It's possible that -- I have a long publication list, and some of those publications have looked at complications, and so it's possible that those may have been somewhere buried in some articles. So I wouldn't completely rule it out, but I can't think of an example right now.
Q. The calculations you performed in this case looked at the frequency of complications, I believe you told us?
A. I looked at relative risks that were reported.

Q. And by relative risks that were reported, you mean relative risks based on the frequency of complications reported in one filter versus another filter?

A. As we've defined it, yes.

Q. And as I understand it, the relative risks you looked at were only between the Recovery filter and the Simon Nitinol filter or between the G2 filters and the Simon Nitinol filter; correct?

MR. MANKOFF: Object to form.

A. For the purpose of this case and this analysis.

Q. And you did not do any comparable relative risk analysis between Bard filters and competitive filters; correct?

A. So first, I want to again be careful with the language. These are reporting relative risks or reporting risk ratios, as I call them, but -- so that's what we're dealing with.

And for this case, that's correct.

Q. What's the significance of that limitation, reporting risk ratios?

MR. MANKOFF: Object to form.

Q. Or relative risks, reporting relative risks? I'm sorry.

A. Because I just want to be clear that the basis of the analysis and the basis of the estimates are based on what is reported.

Q. And that limitation, does that impact the accuracy of those relative risks?

MR. MANKOFF: Object to form.

A. It means that I have to be careful in interpreting them; and when you say accuracy, of course, you have a target in mind, and as far as how closely they estimate the true or actual risk ratio, so that's a consideration that needs to be thought through.

Q. Now, what sort of complications were -- did you look at, as far as relative risks?

MR. MANKOFF: Object to form.

A. So I'm going to -- may I look at my --

Q. Yes.

A. So I looked at maybe six. So I looked at filter embolization deaths, migration events, caval perforations, filter fractures, tilted filters, and then combinations of some of those.

Q. In calculating these reported relative risks, did you break them down as to specific complications? Did you analyze a reported relative risk for the Recovery filter versus Simon Nitinol

Q. But it was clear, even if you didn't perform the exact calculations, it was clear that the frequency of these reported adverse events was not huge; correct?

MR. MANKOFF: Object to form.

A. Correct, relative to the reported sales numbers and the reported events, that's correct.

Q. Now, you've been using and we've been using interchangeably as you said reported risk ratio, that term, with reported relative risk. How does a reported relative risk differ from a relative risk?

A. So the qualifier "reported" is important, and that's indicating that the data are coming from reports, and are not being derived from a beautifully run and designed experiment like a clinical trial, in which there's perfect follow-up and in which it's really a true experiment.

So the "reporting" qualifier is there to say and to suggest that these are numbers that are reported. These are based on reports.

Q. And that's different from a true relative risk; correct?

A. A relative risk, which is what the target is, which is what would be of interest, wouldn't be entangled with issues around reporting.

Q. And we don't know whether that occurred in this instance with this particular data set, do we?

MR. MANKOFF: Object to form.

A. We don't whether what occurred?

Q. Underreporting or overreporting. You said it could lead to it.

A. No --

Q. We don't know whether it led to either way in this case, do we?

A. I'm sorry; I said --

MR. MANKOFF: Just let the court reporter catch up.

Object to form.

A. Okay. I didn't say anything about overreporting. What I said was overestimates. So these data could -- they provide an estimate, we call it the reporting risk ratio. And this estimate could be an overestimate or it could be an underestimate.

Q. Okay, and I stand corrected. Let me rephrase that question.

And we cannot say, sitting here today, whether the reported relative risk that you calculated overestimates or underestimates in this particular data set, can we?

you were to give, you know, implant these devices in millions of people and then compare, have a perfect, beautiful experiment and compare risks of events, that would be pretty much close to or exactly equal to the so-called true relative risk, the population level theoretical relative risk.

Any smaller study or sample that's used, its whole purpose being to try to estimate or make inference on that population level relative risk, or reported -- I'm sorry; relative risk or risk ratio, is an estimate of that truth.

So I'm making the distinction, I'm being careful to make the distinction between the data, which in any case just provide an estimate. Any data in any context, whether it's a clinical trial or anything, any data allow us to estimate; and what we try to estimate is something true and theoretical, and at a population level.

Q. And when it's based on reports, when the data is based on reports, it can be even more of an estimate than otherwise; correct?

MR. MANKOFF: Object to form.

A. That's part of the -- it's part of the estimation. It's part of the messiness of the data. There's lots of messiness in even perfect, beautiful

clinical trial data. There's noise; that's what I mean by messiness. There's noise in the data, and that's part of it.

Q. But this analysis that you've conducted, as I understand it, generates a hypothesis, essentially; correct?

MR. MANKOFF: Object to form.

A. So I'm not sure what you mean by "generates a hypothesis."

Q. Well, you have tried to analyze the reported relative risk, and if I understand what you're saying, you think that generates a hypothesis as to what the relative risk itself may be.

MR. MANKOFF: Object to form.

Q. Or maybe you don't. You tell me.

A. I don't know what you mean by "hypothesis." "Hypothesis" is a very technical term for a statistician, and so I don't know how to interpret what you're saying.

Q. Tell me what that means to a statistician, "hypothesis."

A. A hypothesis would be a statement about the truth, about truth in the world.

Q. I understand you to say a hypothesis is a truth in the world?

Q. Other than that, you did not review regulations, did you?

A. No.

Q. And you have not yourself reviewed the underlying data for the data set you've used; right?

A. That's not correct.

So the company provided, as we've discussed, many summary sheets that listed, much as I have done, a first tab with all of the data put together with the counts of the adverse events and sales numbers.

And then separately within each subsequent tab, they list it out by device or by filter, in many cases individual-level data. So individual people who reported adverse events. So line by line, those are listed out. I reviewed several of those, as well as the Excel calculations that were used to translate from those individual listings to the summary data, and found mistakes, but I definitely did review those individual-level data.

Q. Are you aware of the fact that Bard prepares a detailed investigation report for every adverse event that's reported?

A. I would only -- I assume that to be true.

Q. And you didn't review those lengthy reports for each individual event, did you?

A. No.

Q. What P-value is recognized as the standard for statistical significance?

MR. MANKOFF: Object to form.

A. Very typically a P-value of .05 -- or a threshold of .05 would be used as a threshold for significance. It's arbitrary, but that's commonly used in some settings.

Q. Let's look at Exhibit 4.

A. Yes.

Q. Look under Tilted Filter, with the Fisher's exact P-values.

A. Yes.

Q. Do any of those rise to the level of .05?

MR. MANKOFF: Object to form.

A. Yes. The highlighted ones, the six highlighted ones do.

Q. And excuse my ignorance here; I'm missing something. Like the first one for Recovery versus SNF on November 9 is .0005 here on the chart; correct?

A. Correct.

Q. How is that greater than .05?

(Question read.)

A. I don't have the documents to show what Bard -- any steps that Bard took. All I have are the end results, which are, the results are what they -- any steps that they would have taken, what they would have been trying to target.

So all I see are the very end results, and those don't -- it's not just that they're not consistent over time; they're actually increasing over time. So those aren't supportive of any steps, but it is correct that I have not seen the Bard documents about remediation steps, regarding reporting.

Q. Okay; let's look two paragraphs down there. The sentence begins, "While there are several potential limitations with the available data sources that must be considered."

What are these potential limitations?

A. Okay; so I think we've talked about some of them. I put them on my list to remind myself to make sure to discuss them.

So underreporting is a potential limitation of any such database, whether it's the FAERS database or the MAUDE database or a company database.

So then the question in evaluating any of these is, well, what difference does it make? So with regard to underreporting, it really actually makes no difference at all unless it's differential underreporting. So in other words, if one product is underreported more than another product, that's where there would be a problem.

But if every product is just -- if adverse events for this patient population are just uniformly underreported in some way and consistently so across products, then that would not be a limitation.

Q. What are other limitations, potential limitations?

A. So another limitation are the data errors. So I found several errors -- counting errors, Excel errors, that kind of thing -- in the Bard data sheets, and I've listed out some of them. Some of them are pretty considerable.

So there's, for example, on the November -- on the data sheet that is cumulative through November 2007, there was sort of a blatant Excel error that counted Recovery migrations to be zero, when in fact once that error in the Excel calculation is corrected, there were 37 of them. So

there's several instances of that.

There's instances of counting the tilted filters but not the filter tilts; so in other words, misidentifying text fields and not including clearly the same event, which was just flipped in the tilter filt (sic) versus the tilted -- sorry; the filter tilt versus the tilted filter.

So anyway, there are many of these data errors, and in fact, they're -- in my review, and like I said there are many instances of these, there are more of them for Recovery than for SNF.

And I think the reason for this is that there are just more listings, individual listings, which leads whoever is putting the spreadsheet together to use Excel formulas, and we all know that you can easily go wrong with these Excel formulas.

And the other thing is that I would say that in every instance that I found of one of these errors, it was always an undercount, so the error was always leading to an undercount of Recovery of events, whether it was migration events or tilted filters or filter embolization deaths. So there were always undercounts.

So that's another problem with the database.

respect to that is just looking at the sales data over time across ten years of time for some products, and less so for others because they were removed from the market earlier. The sales data seems pretty constant month by month, which is the granularity at which I have the data.

So I would imagine that these are expensive devices and nobody wants too many of them sitting on the shelf; and so over time, institutions or physicians learn better how to estimate their needs, and so that wouldn't be a very big problem.

So I did also address that through one of my sensitivity analyses, and just assumed -- or just considered what would happen if I discounted the sales data by 20 percent and just assumed that 20 percent are sitting on the shelf and 80 percent are implanted, and I obtained comparable results to when I didn't do that discounting.

Q. Other limitations?

A. So another limitation is that these are crude estimates of risk and reflect different times of exposure to devices, partly due to when the SNF, for example, was available prior to the start time of 2000; also reflecting the permanent versus retrievable issue.

Q. Have you spoken with any of the other experts in this case?

A. I'm sorry; would you like me to continue with my list?

Q. Oh, yes, I'm sorry; more potential limitations.

A. Let's see.

So the other potential limitations to consider in any of these types of analyses would be any kind of confounding due to patient-level characteristics, and I was unable to address those head-on because patient-level characteristics are not part of the data sheets or the data reports from Bard. So that is always an issue in every single analysis.

Again, it would seem -- and that could go in different directions.

It would seem that typically that has -- across, over many, many different kinds of these analyses across such observational databases, it tends to have a small, could make a small difference. So with reporting risk ratios of 100 or 200 or 40, I feel pretty confident in believing that it's not going to put them below 1. It may move them a little bit, even if there is confounding, and

I don't even know that there is; it's just something that any statistician should think about.

Q. So we just don't know whether there are confounding factors like you're discussing now one way or the other, do we?

MR. MANKOFF: Object to form.

A. I don't know if there are.

Q. Other limitations?

A. So then within these spontaneous reporting, as they're called, databases -- the FAERS or MAUDE -- there's always a potential that there's increased reporting when a product first launches or that there's increased reporting surrounding some kind of notoriety.

It doesn't seem to be the case here, and especially since, my understanding is there's no FDA warning that was published which in other cases is really what is associated -- what has been seen to be associated with notoriety, when the FDA comes out with some kind of a warning letter or something like that.

Q. Doesn't attorney advertising for litigation involving a product contribute to notoriety that may influence these numbers?

A. I don't know. I don't know the extent to

MR. ROTMAN: Can I see it?

(Marked, Exhibit 6, typewritten notes made by the witness.)

MR. ROTMAN: Richard, is it okay to take a short break?

MR. NORTH: Mm-hmm.

MR. ROTMAN: Thank you.

THE VIDEOGRAPHER: The time is 12:13, and we are off the record.

(Recess)

THE VIDEOGRAPHER: We are back on the record. The time is 12:17.

Q. Doctor, in view of these limitations we were talking about right before the break, have you been able to identify or calculate a rate of error for your calculations?

MR. MANKOFF: Object to form.

MR. ROTMAN: Can I have the question reread?

(Question read.)

A. So no, as I have listed, there are many different potential limitations which can go in different directions. I can view each one by itself and make a comment on, for example, what the difference in reporting probabilities would have to

be between two products in order to observe a reporting risk ratio of 288 if the true ratio should be 1, for example. So I can draw conclusions such as that.

But to come up with a single measure of bias relative to a true risk ratio is not even -- not possible here.

I think on the other hand, I do feel comfortable -- while the estimate we recognize is not the truth and is different in some ways from the truth, I do feel comfortable in concluding that it is different from 1, that it's communicating a risk ratio greater than 1 for Recovery versus SNF, for example, and for other products versus SNF.

Q. You just said it's communicating a risk ratio. Wouldn't it be more accurate to say it's communicating a reported risk ratio?

A. No, I'm actually saying it's communicating a risk ratio. So we have the reporting risk ratio, and -- of 200 or 100 or 40, and I agree that there are potential limitations with that estimate. It's just an estimate, and there are various factors that I've listed that influence that estimate.

So I'm not concluding that the estimate is the true risk ratio, in other words, that the

estimate.

An estimate, we also call it a point estimate; it's just a single number. The confidence interval tells us, gives us an interval, of course, about which we can be 95 percent certain that the truth lies within that interval. So that provides a measure of the variability.

So all of those statistical analyses that are contained here, the P-values and the confidence intervals for the through-2010 case, are all about accounting for randomness and error. What they don't do -- which was my original response.

But what they don't do is account for potential, these potential external limitations, which can't be addressed exclusively by the numbers on the page.

And so for those, there's additional error or overestimation/underestimation, and that's not part of the error that is accounted for in these sheets.

Q. Had you done an analysis like this, or someone done an analysis like this, and submitted it for publication to meet publication standards of statistical analysis, would any different kind of error rates be calculated?

nature of any underreporting or lack of detection.

So anyway, putting it all together and thinking about directionality, thinking about everything, I would have to -- I do conclude that it's not 1.5, it's hard to pin down a number, and I don't want to pin down a number, but it would have to be, in my opinion, very likely to be something much larger than 1.

Q. And do you hold that opinion to at least a reasonable degree of scientific and statistical certainty?

A. Yes, I do.

Q. Now, you were asked about some specifics about the plaintiff in this case, Ms. Austin. Do you recall that?

A. Yes.

Q. And you were asked about what type of -- if you knew what type of filter Ms. Austin had implanted --

A. Yes.

Q. -- and what kind of complications she had.

Was it important to you to review the medical facts or the medical records for Ms. Austin for purposes of your analysis?

A. No, it wasn't. So I'm a statistician, I'm

a statistical expert, I'm not a medical expert, and my task was to compare the set of filters as compared to this predicate SNF.

And so the details didn't really matter.

Q. Well, did it matter to you whether she had a Recovery filter or a G2 filter or an Eclipse filter?

A. No. That doesn't make any difference.

Q. Assuming that the evidence at trial is that Ms. Austin had a G2 filter, would that affect your analysis or your opinions?

A. No.

Q. Would it affect how you would undertake your analysis?

A. No.

Q. You were also asked questions about the magnitude of the reported complication frequency. I believe Mr. North said it's 1 percent or 2 percent, certainly less than 50 percent. He used the term small, not large. Do you recall that? Do you recall that?

A. Yes.

Q. In your opinion, is that a meaningful observation, the size of the frequency of adverse event reports as compared to sales --

MR. NORTH: Objection to the form.

Q. -- or as compared to some exposure measure?

A. So the absolute numbers are not -- certainly not as important as comparisons. So a product should only be available if it's just as safe as every other product, or not too much less safe than any other product.

And I didn't look at those individually, as I mentioned previously, because looking at those individual numbers, frequencies, is much less robust than looking at ratios, for example, such as I've done. Because in looking at ratios, as I've discussed previously, any kinds of -- many kinds of potential underreporting or potential discrepancy between sales and implantation washes out in a ratio, whereas it doesn't wash out in the absolute numbers.

So I wasn't interested and didn't look at those or focus on those in any way.

Q. If you're looking at reporting rates, as you were, as my understanding that's what you were looking at, rates of reports of adverse events -- correct?

A. Yes.

Q. -- what does that tell you, if anything,

about the actual complication rate or adverse event rate?

MR. NORTH: Objection to the form.

A. So again, there's the link -- or the leap, I should say, between the reporting rates or risks and the actual risks. And so there may be a discrepancy there. There may be underreporting. There's likely underreporting.

And then, it's the differential underreporting that matter in the comparisons, and that doesn't go away. The underreporting doesn't go away from an absolute estimate. So it makes it even more difficult to interpret those absolute estimates of risk.

Q. You were asked a question about whether you went beyond the internal documents with adverse event data to the actual medical literature to extract adverse event data and to include that as part of your analysis. Do you recall that?

A. Yes.

Q. And I believe you testified that it would not be a good statistical practice to do that?

MR. NORTH: Objection to the form.

Q. Do you recall that?

A. Yes.